MINUTES OF THE IDAHO STATE BOARD OF PHARMACY APRIL 28, 2011

ISU/POND STUDENT UNION BLDG - POCATELLO, IDAHO

This meeting of the Board is held to conduct regular Board business.

Chairman Holly Henggeler, Pharm D, called the meeting to order on April 28, 2011 at 8:08 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; and Rich de Blaquiere, Pharm D; Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Andy Snook, DAG; Fred Collings, Chief Investigator; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

The minutes of the March 3 & 4, 2011 Board meeting were reviewed. Dr. Chopski motioned to approve the minutes of March 3 & 4, 2011, with minor corrections. Dr. de Blaquiere seconded. The motion carried unanimously.

Mr. Johnston explained that the resultant Board direction from today's rule review will be incorporated in a draft that will be released to the public as early as the week after next. Mr. Johnston will send a request to the Department of Administration to publish a notice of intent to rule make in the May Idaho Bulletin, directing the public to a draft of the rules on the Board's web site, so that public comment may commence. Dr. Henggeler directed Mr. Johnston to have two (2) negotiated rule making sessions before the June Board meeting and another two (2) before the October Board meeting. Dr. Chopski requested that there be no further reorganizing of the rules. Mr. Fraser agreed, considering there would likely be changes made once public comment has been heard.

Mr. Johnston noted that the Legislature helped the Board realize that the Out of State Mail Service Pharmacy Licensing Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act are all independent acts. The definitions from the Idaho Pharmacy Act cannot be used in these separate acts. This realization has caused a few issues that will require further attention. The draft rule entitled Scope and the Legal Authority lists statues that authorize rule promulgation. In addition to the Controlled Substance Act and the Pharmacy Practice Act, a reference to the Idaho Legend Drug Donation Act and three references to the Idaho Wholesale Drug Distribution Act must be added.

Dr. Henggeler directed Mr. Johnston and Ms. Lynette Berggren, contracted paralegal, to begin the agenda item entitled legislation and rule review. After much discussion, the Board directed the following changes to draft rules:

000: added additional citations to rule promulgation authority.

- 002: added reference to statute authorizing public records requests.
- 003.01: changed "facsimile" to "fax" (here and throughout remainder of rules) and removed reference to "Rule 5."
- 010.10: added "and is part of a hospital system" to the definition of central order entry pharmacy.
- 010.12: revised definition of centralized pharmacy services to separate dispensing from being indicated as a processing function.
- 010.13: changed "the drug outlet" to "a drug outlet" and added "or controlling interest" to the definition of change of ownership.
- 010.28: revised definition of "drug therapy management" to "selecting, initiating, or modifying drug treatment".
- 010.33: deleted definition for "flavoring agent", as the Board determined that flavoring of a prescription is clearly not compounding, exists today, and is allowed unregulated. This deletion necessitated a numbering revision.
- 010.43: removed the word "and" in a housekeeping effort.
- 010.47.c: deleted the words "drug therapy" from the definition of medication therapy management.
- 010.53: replaced "intravenous or intramuscular administration" with "injection" in the definition of parenteral admixture.
- 010.54: revised the definition of pharmaceutical care to read: "participation by a pharmacist in the provision of drug therapy management, MTM, or other pharmaceutical services" Changed "medication therapy management" to MTM here and in two other places.
- 010.55 & 010.56: removed the word "preceptor" from both definitions and replaced with "pharmacist", also in 250.01.b.
- 010.59: removed the phrase "or for a patient's immediate need for dispensing by a pharmacy or prescriber" from the definition of prepackaging.
- 010.60: added a new definition for "prescriber drug outlet" and revised impacted numbering.
- 010.63: deleted definition for "quality-related event" and revised impacted numbering.

- 010.67: changed "and is not a pharmacy" to "that is not a pharmacy", in a housekeeping effort.
- 010.69: added definition for "secured pharmacy" (consistent with language in rule 204).
- 010.71: deleted "for residents who require medical or nursing care or rehabilitation services for injured, disabled, or sick persons" in a housekeeping effort.
- 010.74: revised definition of "Telepharmacy" to "the practice of pharmacy through the use of telecommunications and information technologies provided to patients at a distance."
- 010.84: replaced "veterinary drug outlet" with VDO.
- 011.01: deleted proposed language in its entirety as extraneous.
- 012.03: changed "enforcement or disciplinary action" to "enforcement of disciplinary action", in a housekeeping effort.
- 015.03: deleted last sentence, as extraneous.
- 016.02: revised list to separate pharmacist intern and pharmacist extern categories to clarify renewal requirements.
- 016.03.h: corrected numbering of subsections (vii to vi). Changed "clinic" to "prescriber drug outlet", as "clinic" was too narrow a term considering 2011 statute changes.
- 020.02: added "or conduct research with", in a housekeeping effort.
- 024: changed from: "unrestricted Idaho license to prescribe, dispense, or administer controlled substances and" to: "unrestricted Idaho license to manufacture, distribute, or dispense controlled substances, as defined in the Uniform Controlled Substances Act, and" in a housekeeping effort.
- 025 & 023: changed "except as provided therein for coincident activities" to "except as provided in federal law", in a housekeeping effort.
- 035: deleted "for self-use or" and added "a controlled substance prescription drug order written for the prescriber's self-use must not be filled", as the intent of current rule #454 was not adequately retained.
- 037: switched subsections 03 and 04 and revised title of new subsection 03 to "schedule II partial-fill documentation" in a housekeeping effort.

- 038: changed "facsimile" to "fax" in a housekeeping effort.
- 039.02: removed "be" in a housekeeping effort.
- 045.01: added the word "drug" before "order" for consistency with 045.03.a. (referring to the "telephone drug order form") used by veterinarian drug outlets. Added "or documented" to contemplate verbal orders.
- 045.03 & 045.04: switched two sections and renumbered, in an effort to organize.
- 045.03.a: added "official" and "three (3) part" in the form description for consistency with 045.01 and replaced "completed form" with "copy one (1) original" when referring to veterinarian drug orders.
- 045.03.c: added "handling and", in a housekeeping effort.
- 045.03.d: added "upon receipt" to last sentence, inserted "veterinary" before drug order, and added "numbered" before "copy one", in a housekeeping effort.
- 045.04.f: deleted "address" and "telephone number" from the requirements of a veterinarian drug order.
- 050: removed "and except in hospital pharmacies", as changes to 50.03 eliminated the need.
- 050.03: changed from "each step of prescription drug order handling" to "each system function in prescription drug order processing", thereby only requiring documentation for functions that are performed within the electronic record keeping system.
- 050.04.b: in an effort to organize, revised to say "functionality that documents . . . ".
- 055.03: deleted "evidenced by written policies and procedures", as extraneous.
- 055.04: added "pharmacist" and "prescriber" as persons authorized to fill an Automated Dispensing and Storage System (ADS).
- 055.05: added "the drug expiration" to list of required info that an ADS must be able to generate.
- 055.06: removed beginning phrase "in addition to any records required by other laws", as extraneous.

- 055.07 & 055.08: deleted "b." which read: "lot numbers may not be mixed" in a ADS.
- 056.11.c: changed "resolution" to "resolving", in a housekeeping effort.
- 057.05.c.ii: added "as" to the beginning of the phrase, in a housekeeping effort.
- 057 & 061: deleted "system downtime and" in a housekeeping effort.
- 058: moved subsection 02 (requirement to prominently display name, etc., on the ADS system) to 057.07 and made applicable to nursing home use only. Moved subsection 01 up to 055.07 and added 058 as a reserved section, in an effort to organize.
- 061.02: revised as follows: "when a generic is selected by a non-institutional pharmacy", to exempt institutional pharmacy from certain drug product selection documentation requirements.
- 062: deleted proposed language in its entirety.
- 064: deleted proposed language in its entirety.
- 070.04: changed "may" to "must", deleted "that enables their production upon lawful request" and changed "and that links" to "and must link" in a housekeeping effort.
- 071.04: replaced "section 37-2723, Idaho Code" with "federal law" in a housekeeping effort.
- 073.02: revised prescriber restriction to read: "prescribing a controlled substance for oneself or administering or delivering a controlled substance to an immediate family member when contrary to the prescriber's scope of practice or prescriptive authority is prohibited" in order to retain intent of current rule 454.
- 086.02.a: deleted proposed language in its entirety.

Dr. Henggeler called the meeting to order after a lunch break.

Legislation and Rule Review discussion continued;

- 086.05: rearranged order and revised language flow in an organizational effort.
- 086.06: separated and revised to add language indicating a single registration is required per facility for "hoods".

- 093.06.d: added "perform prospective drug review and" as per 2011 statute changes.
- 104: deleted proposed requirement to notify "prior to June 1 of each year" and subsection 01. due to redundancy with rule 020.01.and restructured rule appropriately.
- 111.03: added the word "final" before "expiration" to reiterate that tech-in-training registrations are renewable just once.
- 151.01: deleted first clause, changing to "a new pharmacy location" in a housekeeping effort.
- 151.02: deleted "or a change of pharmacy location to another existing Idaho pharmacy" in a housekeeping effort.
- 160: un-struck "parenteral admixture" in opening paragraph, as a valid limited service outlet.
- 160.02: reworked "awkward" language in a housekeeping effort.
- 201: changed "drug outlet" to "pharmacy" in a housekeeping effort.
- 202.02: deleted the word "licensed" as extraneous.
- 212.02: moved depoting rule to 094 and re-titled: "prescription delivery restrictions" (and restructured remaining Rule 212.) in an organizational effort.

Dr. Catherine Cashmore, Associate Professor of Pharmacy Practice at Idaho State University (ISU) commented regarding ISU immunization training. ISU's college of Pharmacy currently teaches a 3 hour course, more than nurses or physician assistants obtain from ISU. Dr. Cashmore believes the APHA, 20 hour training course is excessive, and ISU's course covers the training requirements in current rule #166: Immunization Record.

- 220.02.a: deleted proposed language "practice-based."
- 240.09: deleted language: "the type and size of the customer, and where and to whom the customer distributes its product (if applicable)", as extraneous.

- 240.10: corrected typo in title and added "rebuttable presumption" language.
- 250.02.a: added "pharmacist" before "intern" and "extern" in a housekeeping effort.
- 302: deleted "compliance with these minimum standards and" in a housekeeping effort.
- 302.01: deleted thirty (30) days prior requirements, in a housekeeping effort.
- 304.03: reverted to original language.
- 402.01: deleted "and reviewed and updated as necessary", as extraneous.
- 414 & 415: deleted "institutional facility" from title and switched the order of 414 &
 415 in a housekeeping effort.
- 417.02: replaced "in a pharmacist absence" with "by these rules for institutional facility emergency drug access" in a housekeeping effort.
- 431.02: deleted extra, redundant reference to documentation requirement.
- 550.03.c: deleted proposed language "and any communications with health professionals, consumers, or their agents pertaining to provided products or services", as too burdensome to Durable Medical Equipment (DME) outlets and corrected ending punctuation.
- 613: replaced "an official compendium" with "the USP" in a housekeeping effort.

The Board approved of the rule changes via unanimous consent.

Karl Johnson, a student pharmacist from ISU, commented on immunizations, and he feels that as a fourth (4^{th)} year student he received adequate immunization training.

Julianne Ramirez a student pharmacist from ISU, also commented on immunizations, and she feels the current curriculum is adequate.

At the request of the Board, Ms. Berggren presented information regarding quality improvement and quality assurance programs in pharmacy practice. Ms. Berggren started by giving background information on various study methods and approaches,

including those most often used in pharmacy practice, and then she outlined pros and cons, discussing the various, and sometimes confusing, names assigned to such processes. Ms. Berggren also discussed current mandated programs from other states, including their pros and cons, and she defined critical elements. North Carolina's quality improvement program was used as an example of how to "do it right". Ms. Berggren concluded the presentation by discussing the federal government's approach and discussing alternative approaches.

Gary Pullen R.Ph., of Prescription Center Homecare reported that Mountain View Hospital has purchased an oncology group in Idaho Falls. The hospital has requested that Mr. Pullen's office be involved in preparing sterile chemotherapeutic admixtures for infusion at the physician's offices, not located within the hospital. The oncology physicians would supply Mr. Pullen's pharmacy with chemo agents, and the pharmacy would then prepare the sterile chemo admixtures, delivering the admixtures back to the oncology group for use. Mr. Pullen believes that pharmacy involvement is superior to the current practice of technicians preparing admixtures at the office, and the Board agrees, discussing the limitations of the Idaho Wholesale Drug Distribution Act. Nancy Lundblade R.Ph., the pharmacist in charge at Mountain View Hospital Pharmacy also spoke in regards to the benefits of Mr. Pullen providing the proposed services. After a lengthy discussion the Board determined that if the Rx items were shipped to Mr. Pullen's pharmacy directly from the wholesaler, he would be working within law.

Mr. Johnston presented the Board's financial report for the Board office:

- Personnel costs are right on track, with 80% of the budget year lapsed and 80% of personnel cost spent.
- Operating expenses are under budget with 80% of the year lapsed and 69% of the budget spent. Because of efficiencies realized, the operating budget continues to see excesses, and Mr. Johnston would like to request reappropriation of some monies to personnel in the 2013 budget.
- Capital outlay expenditures appear drastically under spent, as they don't currently reflect the expenses for the new vehicles that Mike Brown and Lisa Culley will use for inspections. One was just delivered, and the second is still on order.
- The cash fund balance appears low, because the Board is currently between renewals. Once spring renewals are complete, the balance will return to approximately 1.9 million dollars.
- A small amount of federal grant money has been spent on the purchase of a laptop for Teresa Anderson, PMP Program Manager. Decisions regarding the remaining balance should be made around the end of the fiscal year, after attending the Alliance of States with Prescription Monitoring Programs' and the National Association of boards of Pharmacy's annual meetings, where details of the two proposed interstate data sharing programs will be explained.
- The new office lease agreement is in place, and the new office is currently being remodeled to accommodate the staff's space needs. The projected move date is June 11th.

Mr. Johnston presented the travel calendar. Mr. Johnston taught 2 continuing education classes just prior to and will present another continuing education class just after the Board meeting today. Ms. Anderson will be attending the National Meeting on Practitioner Education/PMP Utilization, which will be funded by the federal grant. Mr. Johnston, Dr. Henggeler and Dr. Chopski will be attending the Annual NABP meeting in San Antonio, TX in May. In June, Mr. Johnston will conduct a negotiated rule making session as well as teach a continuing education class at the ISPA's NW Convention. Mr. Johnston and Ms. Anderson will be attending the Alliance of States with PMP's Annual meeting in Washington, DC to which the federal grant will pay for two (2) individuals to attend. Mr. Johnston will also attend the DEA's June conference in Fort Worth, TX. The next Board meeting is on June 16th. Ms. Marcus requested that the Board meeting scheduled for August 4th & 5th be rescheduled. After a discussion the Board determined that the dates could not be changed. Ms. Marcus will see if someone from her office will be available to be at the meeting in her absence.

Dr. Henggeler would like the Board to complete Mr. Johnston's performance appraisal during executive session at the next Board meeting and the managing Board staff to complete Board staff appraisals. Mr. Johnston explained that the Department of Human Resources is in the process of changing the appraisal policy, and the new policy may not be ready in time for the next Board meeting. Dr. Henggeler requested that the Board be notified when the new policy has been updated.

Mr. Snook represented the Board in the matter of Mr. Allen Frisk's, R.Ph. reinstatement hearing. Mr. Frisk represented himself. After a lengthy discussion with the Board members, Dr. de Blaquiere motioned that Mr. Frisk be allowed reinstatement with the restrictions that he can work in the practice of pharmacy up to 16 hours a week and that he cannot dispense medication. In addition, Mr. Frisk would have to apply for full reinstatement at the end of his current suspension: there will be no automatic reinstatement. The motion died for lack of a second. After further lengthy discussion that included Ms Marcus and Mr. Snook, Mr. Fraser motioned that Mr. Frisk be allowed reinstatement with the restriction that he can work in the practice of pharmacy up to 16 hours per week and that he cannot dispense medication, subject to one (1) year of probation. Dr. de Blaquiere seconded the motion. Dr. Chopski requested amendment to Mr. Fraser's motion in that Mr. Frisk also be required to submit quarterly statements from his attending physician, that he contract with Southworth Associates, the administrator of the Board's pharmacy recovery network (PRN), to complete an inpatient evaluation, and that he must be in compliance with any program requirements developed at said evaluation prior to activation of his license and registration. Mr. Snook asked that the motion include standard language used in many stipulations. Mr. Fraser accepted Dr. Chopski and Mr. Snook's request for amendment. Mr. Snook clarified his request as requiring Mr. Frisk to provide a list of employers, notify the Board in writing of any change in place of practice or business within 15 days, notify the Board if residing or employed outside of the state of Idaho, and that he fully cooperate with the Board and its agents. Mr. Fraser clarified his motion. Dr. Chopski seconded. The motion passed unanimously.

Dr. de Blaquiere and Mr. Johnston left the meeting. A quorum still remains.

Mr. Snook presented case number BOP 11-041, stipulation and consent order regarding the pharmacist license and controlled substance registration of Robert Floto R.Ph., involving violations of Idaho Code 37-2722(c), 54-1726(a)&(f), and violation of rule #184.08 for diverting controlled substances for his own non-prescribed personal use. Mr. Floto is to continue with the PRN program, and he will not be suspended or fined due to his compliance with the PRN program. Via unanimous consent, the Board voted in favor of accepting the stipulated order as written.

Mr. Snook presented case number BOP 11-017, stipulation and consent order regarding the manufacturing wholesaler registration of Heel Inc., involving violations of Idaho Code 54-1754(2) for providing prescription drugs to a licensed chiropractor and naturopath who did not have prescribing privileges in Idaho. The stipulated penalty included administrative fines of \$14,000.00, \$375.00 in investigative cost, and a written plan of action must be submitted to the Board. Via unanimous consent, the Board voted in favor of accepting the stipulated order as written.

Mr. Snook presented case number BOP 09-617, stipulation and order regarding Valley Co-op Inc., specifically for their Wendell, Idaho location for the retail sale of Rx Items without prescription and for distributing Rx items to their other Valley Co-op locations for subsequent retail sale without prescription. The stipulated penalty included a \$2000.00 fine and a written compliance plan, which was already submitted to the Board. Mr. Snook noted that the Board could see other cases related to the events that have been set forth. Dr. Chopski motioned to accept the stipulation and order as written. Via unanimous consent, the Board voted in favor of accepting the stipulated order as written.

Mr. Fraser motioned to adjourn, Dr. Chopski seconded. The vote was unanimous. Meeting adjourned at 5:10 p.m.